

House Amendment 1269

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1 1 Amend House File 724 as follows:
1 2 #1. By striking everything after the enacting
1 3 clause and inserting the following:
1 4 <Section 1. NEW SECTION. 135M.1 PURPOSE.
1 5 The purpose of this chapter is to improve the
1 6 health of low-income Iowans through a prescription
1 7 drug donation repository that authorizes medical
1 8 facilities and pharmacies to redispense prescription
1 9 drugs and supplies that would otherwise be destroyed.
1 10 Sec. 2. NEW SECTION. 135M.2 DEFINITIONS.
1 11 1. "Anti-rejection drug" means a prescription drug
1 12 that suppresses the immune system to prevent or
1 13 reverse rejection of a transplanted organ.
1 14 2. "Cancer drug" means a prescription drug that is
1 15 used to treat any of the following:
1 16 a. Cancer or the side effects of cancer.
1 17 b. The side effects of any prescription drug that
1 18 is used to treat cancer or the side effects of cancer.
1 19 3. "Controlled substance" means the same as
1 20 defined in section 155A.3.
1 21 4. "Department" means the Iowa department of
1 22 public health.
1 23 5. "Indigent" means a person with an income that
1 24 is below two hundred percent of the federal poverty
1 25 level as defined by the most recently revised poverty
1 26 income guidelines published by the United States
1 27 department of health and human services.
1 28 6. "Medical facility" means any of the following:
1 29 a. A physician's office.
1 30 b. A hospital.
1 31 c. A health clinic.
1 32 d. A nonprofit health clinic which includes a
1 33 federally qualified health center as defined in 42
1 34 U.S.C. } 1396d(1)(2)(B); a rural health clinic as
1 35 defined in 42 U.S.C. } 1396d(1)(1); and a nonprofit
1 36 health clinic that provides medical care to patients
1 37 who are indigent, uninsured, or underinsured.
1 38 e. A free clinic as defined in section 135.24
1 39 f. A charitable organization as defined in section
1 40 135.24.
1 41 g. A nursing facility as defined in section
1 42 135C.1.
1 43 7. "Pharmacy" means a pharmacy as defined in
1 44 section 155A.3.
1 45 8. "Prescription drug" means the same as defined
1 46 in section 155A.3, and includes cancer drugs and anti=
1 47 rejection drugs, but does not include controlled
1 48 substances.
1 49 9. "Supplies" means the supplies necessary to
1 50 administer the prescription drugs donated.
2 1 Sec. 3. NEW SECTION. 135M.3 PRESCRIPTION DRUG
2 2 DONATION REPOSITORY PROGRAM AUTHORIZED.
2 3 1. The department, in cooperation with the board
2 4 of pharmacy examiners, may establish and maintain a
2 5 prescription drug donation repository program under
2 6 which any person may donate prescription drugs and
2 7 supplies for use by an individual who meets
2 8 eligibility criteria specified by the department by
2 9 rule. The department may contract with a third party
2 10 to implement and administer the program.
2 11 2. Donations of prescription drugs and supplies
2 12 under the program may be made on the premises of a
2 13 medical facility or pharmacy that elects to
2 14 participate in the program and meets the requirements
2 15 established by the department.
2 16 3. The medical facility or pharmacy may charge an
2 17 individual who receives a prescription drug or
2 18 supplies a handling fee that shall not exceed an
2 19 amount established by rule by the department.
2 20 4. A medical facility or pharmacy that receives
2 21 prescription drugs or supplies may distribute the
2 22 prescription drugs or supplies to another eligible
2 23 medical facility or pharmacy for use pursuant to the
2 24 program.

2 25 5. Participation in the program shall be
2 26 voluntary.

2 27 Sec. 4. NEW SECTION. 135M.4 PRESCRIPTION DRUG
2 28 DONATION REPOSITORY PROGRAM REQUIREMENTS.

2 29 1. A prescription drug or supplies may be accepted
2 30 and dispensed under the prescription drug donation
2 31 repository program if all of the following conditions
2 32 are met:

2 33 a. The prescription drug is in its original sealed
2 34 and tamper-evident packaging. However, a prescription
2 35 drug in a single-unit dose or blister pack with the
2 36 outside packaging opened may be accepted if the
2 37 single-unit dose packaging remains intact.

2 38 b. The prescription drug bears an expiration date
2 39 that is more than six months after the date the
2 40 prescription drug was donated.

2 41 c. The prescription drug or supplies are inspected
2 42 before the prescription drug or supplies are dispensed
2 43 by a licensed pharmacist employed by or under contract
2 44 with the medical facility or pharmacy, and the
2 45 licensed pharmacist determines that the prescription
2 46 drug or supplies are not adulterated or misbranded.

2 47 d. The prescription drug or supplies are
2 48 prescribed by a health care practitioner for use by an
2 49 eligible individual and are dispensed by a pharmacist.

2 50 2. A prescription drug or supplies donated under
3 1 this chapter shall not be resold.

3 2 3. a. If a person who donates prescription drugs
3 3 under this chapter to a medical facility or pharmacy
3 4 receives a notice from a pharmacy that a prescription
3 5 drug has been recalled, the person shall inform the
3 6 medical facility or pharmacy of the recall.

3 7 b. If a medical facility or pharmacy receives a
3 8 recall notification from a person who donated
3 9 prescription drugs under this chapter, the medical
3 10 facility or pharmacy shall perform a uniform
3 11 destruction of all of the recalled prescription drugs
3 12 in the medical facility or pharmacy.

3 13 4. A prescription drug dispensed through the
3 14 prescription drug donation repository program shall
3 15 not be eligible for reimbursement under the medical
3 16 assistance program.

3 17 5. The department shall adopt rules establishing
3 18 all of the following:

3 19 a. Requirements for medical facilities and
3 20 pharmacies to accept and dispense donated prescription
3 21 drugs and supplies, including all of the following:

3 22 (1) Eligibility criteria for participation by
3 23 medical facilities and pharmacies.

3 24 (2) Standards and procedures for accepting, safely
3 25 storing, and dispensing donated prescription drugs and
3 26 supplies.

3 27 (3) Standards and procedures for inspecting
3 28 donated prescription drugs to determine if the
3 29 prescription drugs are in their original sealed and
3 30 tamper-evident packaging, or if the prescription drugs
3 31 are in single-unit doses or blister packs and the
3 32 outside packaging is opened, if the single-unit dose
3 33 packaging remains intact.

3 34 (4) Standards and procedures for inspecting
3 35 donated prescription drugs and supplies to determine
3 36 that the prescription drugs and supplies are not
3 37 adulterated or misbranded.

3 38 b. Eligibility criteria for individuals to receive
3 39 donated prescription drugs and supplies dispensed
3 40 under the program. The standards shall prioritize
3 41 dispensing to individuals who are indigent or
3 42 uninsured, but may permit dispensing to other
3 43 individuals if an uninsured or indigent individual is
3 44 unavailable.

3 45 c. Necessary forms for administration of the
3 46 prescription drug donation repository program,
3 47 including forms for use by individuals who donate,
3 48 accept, distribute, or dispense the prescription drugs
3 49 or supplies under the program.

3 50 d. A means by which an individual who is eligible
4 1 to receive donated prescription drugs and supplies may
4 2 indicate such eligibility.

4 3 e. The maximum handling fee that a medical
4 4 facility or pharmacy may charge for accepting,
4 5 distributing, or dispensing donated prescription drugs

4 6 and supplies under the program.
4 7 f. A list of prescription drugs that the
4 8 prescription drug donation repository program will
4 9 accept.
4 10 Sec. 5. NEW SECTION. 135M.5 EXEMPTION FROM
4 11 DISCIPLINARY ACTION, CIVIL LIABILITY, AND CRIMINAL
4 12 PROSECUTION.
4 13 1. In the absence of bad faith, a drug
4 14 manufacturer is not subject to criminal prosecution or
4 15 civil liability for injury, death, or loss to a person
4 16 or property for matters related to the donation,
4 17 acceptance, or dispensing of a prescription drug
4 18 manufactured by the drug manufacturer that is donated
4 19 under this chapter, including liability for failure to
4 20 transfer or communicate product or consumer
4 21 information or the expiration date of the donated
4 22 prescription drug.
4 23 2. Except as provided in subsection 3, a person
4 24 other than a drug manufacturer subject to subsection
4 25 1, is immune from civil liability and criminal
4 26 prosecution for injury to or the death of an
4 27 individual to whom a donated prescription drug is
4 28 dispensed under this chapter and shall be exempt from
4 29 disciplinary action related to the person's acts or
4 30 omissions related to the donation, acceptance,
4 31 distribution, or dispensing of a donated prescription
4 32 drug under this chapter.
4 33 3. The immunity and exemption provided in
4 34 subsection 2 do not extend to any of the following:
4 35 a. The donation, acceptance, distribution, or
4 36 dispensing of a donated prescription drug under this
4 37 chapter by a person if the person's acts or omissions
4 38 involve reckless, wanton, or intentional misconduct.
4 39 b. To acts or omissions outside the scope of the
4 40 program.
4 41 Sec. 6. NEW SECTION. 135M.6 SAMPLE PRESCRIPTION
4 42 DRUGS.
4 43 This chapter shall not be construed to restrict the
4 44 use of samples by a physician or other person legally
4 45 authorized to prescribe drugs pursuant to section
4 46 147.107 during the course of the physician's or other
4 47 person's duties at a medical facility or pharmacy.
4 48 Sec. 7. NEW SECTION. 135M.7 RESALE PROHIBITED.
4 49 This chapter shall not be construed to authorize
4 50 the resale of prescription drugs by any person.>
5 1 #2. Title page, line 1, by striking the words <and
5 2 redispensing>.
5 3 #3. Title page, by striking line 2 and inserting
5 4 the following: <repository program.>
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KURTENBACH of Story
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CARROLL of Poweshiek
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MURPHY of Dubuque
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SHOULTZ of Black Hawk
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5 21 HF 724.202 81
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